PUS-H002-001
Substitute Specification (2nd Pre-Amendment)

FLEXIBLE VERTEBRAL LINKING DEVICE

FIELD OF THE INVENTION

The invention relates to a posterior flexible vertebral linking device which works in tension, compression and flexion, and which damps all mechanical stresses. This device ~~will have~~ has operational advantages that will be described below.

PRIOR ART:

~~We know m~~ Many posterior vertebral attachment units exist which rigidize ~~rigidifying~~ a certain number of vertebrae by depriving them of any mobility, thus ~~allowing the containment of~~ containing all mechanical stresses. However, the first vertebra adjacent to this rigidized block of vertebrae ~~keeps all its mobility~~ remains mobile and, consequently, ~~this~~ there is an abrupt discontinuity in movement between the rigid block and this free vertebra which very often generates a very high stress ~~of~~ in the linking elements. The result is an acceleration of the degeneration of this level (the interface between the adjacent vertebrae and the vertebrae comprising part of the rigidized block).

This problem was only partially solved by semi-rigid systems conceived to create an intermediate rigidity between the mobile vertebrae and the fixed vertebrae. These prior art systems present primarily one of two ~~the following~~ disadvantages, either they work only in tension or they work in compression with a thrust in tension~~:~~ .

As for those that ~~Either: they~~ work only in tension: this is the case of all the devices based on artificial ligaments. These systems ~~are hardly elastic~~ have little elasticity and leave ~~with the discretion of the operator~~ the care to regulate , in particular, the tension, to the skill of the operator, thus ~~in particular~~ making ~~thus random~~ the mechanical characteristics in the operating mode of interest (tension/compression) ~~that concerns us~~ haphazard.

~~Or: they~~ As for those that work in compression with a thrust in tension, ~~which~~ this makes these devices ineffective ~~once they must assist~~ when dealing with displacements in tension ~~extension~~.

In either case: none of the known devices entirely solves the problem which is posed, namely, damping the mechanical stresses existing in tension/compression and flexion to which a moving vertebra ~~can be~~ is subjected

~~We will name the first prior art: patent~~ Patent Application EP 0576 379 A1 ~~which presents~~ proposes a shock absorber which seems to approach ~~the~~ most closely at least from the point of view of the general ~~outline~~ concept of this invention. This patent describes ~~; claim 1 of this patent protects~~ "a uni-axial shock absorber working only in compression while playing the part of an abutment which opposes any displacement of the piston beyond a given value...".

This invention deals with ~~In this case~~ the exponential limitation of the displacement, which ~~solved by the prior art,~~ is a completely different problem as that of the ~~, which has nothing to do with that the person who wants to solve the~~ present invention.

~~We now quote a second prior art: the p~~ Patent application N° 0012998 ~~which~~ describes and claims "a flexible and cast solid vertebral linking device functioning in a multidirectional way". This ~~anteriority~~ prior art reference does not solve exactly the same problem as ~~the one~~ that of the present invention ~~seeks to solve, this invention having~~ due to its different means and functions.

SUMMARY OF THE INVENTION

The invention concerns a flexible intervertebral linking device that meets the needs identified above. The device (1) utilizes two sets of structures. A first structure (11) is a rigid structure (110, 112, 114, 116) preferably made of biocompatible metallic materials providing the device with good mechanical

resistance by integral load transmission without deformation. A second structure (12) is a flexible or damping structure (121 and 122) made of biocompatible viscoelastic materials, permitting repeated elastic deformations, the combination of the two structures providing the device with both resistance and mechanical stress damping of forces to which it is subjected, with the purpose of compensating for any deficiency in the flexibility of certain anatomical links of the human body.

In an advantage, ~~In the present invention, one~~ the surgeon can choose in a precise way the desired working method: tension/compression or flexion, or the combination of the two working methods, ~~this in order~~ so as to avoid any contact between the articular facets.

BRIEF DESCRIPTION OF THE DRAWINGS

~~We will list the drawings which help us understand the invention.~~

Figure 1A and 1B ~~bis of sheet 1/6 presents~~ are perspective views (two alternative embodiments) of the device ~~in the case of a working method combined~~ operating in tension, compression and flexion.

~~The f~~Figures 2A and 2B ~~bis of sheet 1/6~~ are longitudinal cross-sectional views of two alternative embodiments of the inventions ~~of the same device~~.

Figure 3 ~~of sheet 2/6~~ is an exploded view of the invention ~~device and its means~~.

Figure 4 ~~of sheet 3/6~~ is a perspective view ~~in perspective~~ of the invention for operation ~~device working~~ only in tension/compression.

Figure 5 ~~of sheet 3/6~~ is a cross-sectional view of the ~~device working~~ invention operating only in tension/compression.

Figures 6 to 11 ~~of sheet 4/6 represent all~~ are perspective views depicting the individual parts of the invention ~~constituting the device~~.

Figure 12 ~~of sheet 4/6 shows~~ is a perspective view of another ~~specific means working according to the~~ component for operation in the tension/compression mode.

Figure 13 ~~of sheet 5/6 shows~~ is a side, cross-sectional view of an alternative of the device working along two axes.

Figures 14 to 17 ~~of sheet 5/6 show~~ are perspective views of four forms of the mobile end of ~~another~~ other embodiments of the invention ~~alternative of device 1~~.

Figure 18 ~~of sheet 6/6 shows~~ is a side, cutaway view of the invention in place in a patient ~~device in position~~.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT(S):

The device 1 utilizes two sets of structures ~~consists of two sets of means~~: A first ~~set of means~~ structure 11 is a ~~composed of~~ rigid ~~means~~ structure manufactured out of preferably metal, biocompatible material ensuring a good mechanical resistance of the device by completely transmitting the forces.

A second ~~set of means~~ structure 12 ~~formed of~~ is a flexible or damping structure ~~means~~ manufactured out of viscoelastic biocompatible materials, supporting the repeated elastic strain. It is the combination of these two ~~sets of means~~ structures which makes the operation of the invention possible ~~the functioning of the invention.~~

The first ~~set of means~~ structure 11 includes four mechanical structures 110, 112, 114, 116 which have the function of transmitting ~~the~~ stresses to which the device 1 is subjected, without deformation ~~becoming deformed, and to which device 1 is subjected~~.

The mechanical structure 110 is made up of a mechanical rod 111, one of its ends being surmounted by a circular plate 113b connected to the ~~aforementioned~~ rod 111 with a broad joining radius 113a, the ~~whole~~ assembly being able to slide in the ~~hollow part~~ cavity of the structure 114 which encloses a visco-elastic element 121.

The mechanical structure 112 is a cap provided with a thread 117 allowing for the fixing of the ~~aforementioned~~ structure 112 on structure 114; the ~~means~~ structure 112 has a shoulder area 118 which ~~makes possible the enclosure of~~ encloses a viscoelastic-centering ring 121 between itself and the plate 113b ~~and itself~~.

The mechanical structure 114 is made up of two hollow cylinders, one of which is tapped to allow the fixing of a rod 116 with a threaded end. The

mechanical structures ~~means~~ 110 and 116 will be fixed on the vertebrae to permit the functioning ~~allow the operation~~ of the device 1.

The second ~~set of means~~ structure 12 is made up of two viscoelastic components ~~means~~ 121 and 122.

The ~~first means~~ centering ring 121 ~~is~~ preferably ~~a centering ring which lets~~ allows the rod 111 to slide in its center

The second ~~means~~ component 122 is a disc ~~full~~ of viscoelastic material. These two centering rings 121 and 122 can undergo compressive stresses which may not be uniformly distributed~~, t~~. They ~~were conceived~~ are formed to resist many cyclic fatigue stresses without breaking~~.~~. ~~t~~Compressive tests have been performed, which verify that the components ~~were carried out in this direction, means~~ 121 and 122 are able to undergone these tests of elastic deformation as many times as necessary.

The selected material is preferably a biocompatible polyurethane; thanks to their integration inside mechanic ~~means~~ components 110, 112, 114, 116, the viscoelastic ~~means~~ elements 121 and 122 are protected by the preceding mechanical structures ~~of~~ from the aggressive environment of the human body, which avoids in particular the formation of fibers around these ~~means~~ components which could deteriorate the viscoelastic properties of the material and consequently disturb the correct operation of device 1.

This device 1 makes possible the damping of the stresses in tension/compression and flexion which it undergoes by the intermediary of rods 110 and 116. This function is assured owing to the fact that ~~means~~ component 112 has a sufficiently broad opening 119 to allow a clearance of rod 111 and that there is a functional allowance between plate 113 and the hollow body of ~~means~~ component 114; the shoulder area 118 serves as a stop and maintains in its housing the viscoelastic ~~mass~~ element 121 thus constrained ~~locked up~~.

If one wishes to work in a uni-axial mode of tension/compression, ~~means~~ component 112 is replaced by another ~~means~~ component 115 equipped with ~~a threading~~ threads 117, which includes a cap 115c, whose opening 119 is of a diameter which corresponds ~~is adjusted~~ to the diameter of the rod 110 and which is elongated with a ~~while being extended by~~ a ~~guiding~~ rod guide 115a.

This device 1 is thus able to react dynamically to the applied stresses ~~applied~~. Note that it ~~It~~ is essential that structure 114 comprises a bore 114a to allow ~~a~~ for low friction guidance ~~without excessive friction~~ of rod 110 in the aforementioned ~~means~~ component 114.

The adjustment of the diameter of the viscoelastic centering rings 121 and 122 must be selected ~~carried out~~ with precision to enable them to be crushed freely until a stress threshold is reached, this threshold corresponding to a point of contact of the bore 114a of ~~means~~ component 114.

An alternative ~~of the set of~~ ~~means~~ to the structure 11 includes metal structures having the same functions as the structures 110, 112, 114, 116, but the assembly of these three parts (110,130, 131) ~~being of a weaker barrier~~ having a lower threshold than that of the structures previously described (see Fig 2).

The rod 131 is fixed at its cap 130 by the intermediary of a ~~threading~~ thread located on shoulder 132 of the rod.

In ~~the case of~~ this alternative embodiment, the possibilities of displacement of rod 110 subjected to the stresses in flexion are enabled ~~ensured~~ by play 119 located between cap 130 and rod 110.

For a uni-axial operation of device 1, it is preferable to use ~~means~~ components 110, 112, 114, 116 which provide a better guidance of rod 110. If small overall dimensions are needed, ~~means~~ components 110, 130, 131 may be preferably used.

Device 1 is able to function with rods 110 and 131 moving on convergent axes (fig 13) with a small angle of displacement and according to given clearances.

The ~~set of means~~ structure 12 is therefore comprised of two visco-elastic ~~means~~ components 141 and 142. Note that the rod 110 has a flange 110' on its end. The ~~means~~ component 141 is a cylinder ~~full~~ of visco-elastic biocompatible material, ~~and~~ whose face in contact with ~~a plate~~ the flange 110' is inclined. The ~~means~~ component 142 is a centering ring whose face in contact with the back of ~~a plate~~ the flange 110' is inclined.

The ~~set of means~~ structure 11(rigid means) is identical to the previous one that is described above, the orifice 119 being however eccentric depending on the chosen angle. The shape of orifice 119 is defined depending on the clearances ~~which are~~ allowed ~~to~~ with the rod 110.

The rod 110 is thus able, thanks to these new technical characteristics, to function in tension/compression with a given angle with respect to the rod 116 or the rod 131 in the case in which the 119 orifice is eccentric and adjusted to the rod 116 or 131 (see Figure 14).

The rod 110 forming an angle with respect to ~~as against~~ the rod 116 or 131 (the case in which the 119 orifice is oblong and eccentric) can in this case function equally well in tension/compression as in lateral flexion. (see Fig. 15).

The rod 110 can function in tension/compression and in flexion following a preferred axis which can be, for instance, in the sagital plane of the spinal column, and this one on the one side and one the other side of a given position of the rod 110 which, at rest, forms ~~forming at rest~~ an angle with the rod 116 or the rod 131, this also being ~~in~~ the case where the ~~means~~ component 119 is oblong or eccentric, (figure 16).

Finally, the rod 110 can function in tension/compression and in flexion in all directions, forming an angle, as against the rod 116 or 131 in case the orifice 119 is eccentric or larger than the diameter of the rod 110 (see Figure 17).

Multiple variations and modifications are possible in the embodiments of the invention described here. Although certain illustrative embodiments of the invention have been shown and described here, a wide range of modifications, changes, and substitutions is contemplated in the foregoing disclosure. In some instances, some features of the present invention may be employed without a corresponding use of the other features. Accordingly, it is appropriate that the foregoing description be construed broadly and understood as being given by way of illustration and example only, the spirit and scope of the invention being limited only by the appended claims.